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TITLE: Enhancing BATTLEMIND: Preventing PTSD by Coping with Intrusive Thoughts

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14. ABSTRACT Over this award period, data collection for this study was completed; awarded supplemental funding statistical support as well as a research technician was added. We were able to continue our working relationship with Camber Corporation, and have been pleased with the ongoing work that they have been doing on our statistical efforts. Additionally, we have been able to make significant progress regarding the transcription and coding of our qualitative data (intrusive thoughts). This included the addition of a qualitative expert and two no-cost volunteers to the study. Analyses for the primary hypotheses are underway, however we have already begun to synthesize and disseminate preliminary findings via a presentation, a poster, and a completed manuscript. Another Phase 1 manuscript is in progress. Additionally, at the time of this report, a Phase 2 manuscript is in the planning stages and we anticipate that we will proceed quickly with additional dissemination. Finally, we are exceptionally pleased that we have been able to meet the milestones outlined in the SOW to this point and look forward to completing all milestones in the coming year, thanks in large part to the granting of additional funding as well as the ability to extend our period of performance for an additional no-cost year.					
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Introduction

Mandated post-deployment training currently instructs troops on maximizing mental health related to deployment. However, a critical element of successful adjustment is developing adaptive strategies for dealing with intrusive deployment-related thoughts. Intrusive thoughts are a common and upsetting symptom following deployment that are central to posttraumatic stress disorder (PTSD) and have historically been left unaddressed in post-deployment training. This project tests a new post-deployment module that translates evidence-based therapeutic strategies into a resilience-based training module (RESET). RESET specifically educates troops about intrusive thoughts and teaches adaptive skills for long-term coping with the thoughts. This is a two-phase project which tests an enhancement to mandated post-deployment training.

Phase 1, which is complete, included the refinement of the training content of RESET and comparison condition CONTROL (short-term coping strategies). This was achieved with the investigation team and in focus groups with the target audience. **Phase 2** (currently in progress; recruitment and data collection completed and analyses underway) assesses the immediate and short term effectiveness of RESET, CONTROL, and Psychoeducation about Intrusive Thoughts (PIT) as additional post-deployment modules. This was tested in a controlled trial with 4 conditions: RESET, CONTROL, PIT and Training as Usual (TAU).

Keywords

Mindfulness, training, post-deployment, intrusive thoughts

Overall Project Summary

This report details activities for this project during the time period of April 27, 2013—August 31, 2014 (Award period 4). We are very pleased to report that during this award period, recruitment, enrollment, and data collection were completed for 1,533 participants. Originally, we anticipated a total enrollment of 1,600 Soldiers. However, during this award period we requested and received approval to cap study enrollment at 1,533 consented participants; we had made recruitment efforts aimed at all eligible Soldiers including focused recruitment from our target Brigades (3rd Brigade and 10th Combat Aviation Brigade. This request was granted via an executed modification on October 2nd, 2013.

During this award period, we were pleased to have received supplemental funding in the amount of \$179,300 (executed agreement received September 20th, 2013). The purpose of this supplemental funding (requested in November, 2012) was primarily to support the hiring of a statistical team to conduct Phase 2 analyses, which had become significantly more complex since the doubling of the size of the study population as described in our previous annual report. In October 2013 we began receiving bids for statistical services and on November 15th, 2013 we were pleased to award the contract for these services to Camber Corporation. Throughout Phase 2 of this study we had an ongoing relationship with Camber Corporation, as they were previously contracted to print study workbooks and scan collected data. We were pleased with Camber's services and were excited to continue working with them on this effort. Additionally, we were also able to immediately utilize a portion of the supplemental funds increase the effort of our Research Technician, Nina Medoff (for additional detail, see discussion of personnel changes below).

Because there had been a delay in the approval and receipt of the supplemental funds described above, we also requested to extend the Year 4 period of performance for this project by four months (through August, 2013), which would allow us complete the milestones outlined in the SOW. This request was request granted on September 20th, 2013.

In October, 2013, we made a second request for a study extension. Due to the delays in the commencement of the statistical services contract (as a result of supplemental funding delays as described above), the additional time needed to approve Camber staff to begin work, as well as the more complex statistical analyses that were to be performed due to the increase in our sample size (from 800 participants to 1,533) we submitted a modification requesting a no-cost extension of the project through August 31, 2015 (a one-year no-cost extension). We received notification of approval of this request effective April 29th, 2014. Additionally, we requested and received a one year no-cost extension of our contract with Camber (end date to be August 31, 2015).

The quarterly milestones discussed below reflect the current SOW (included with this submission). For ease of reference and clarity, each task outlined in the Statement of Work will be discussed in chronological order.

Award Period 4, Months 1-3

- **RESET, CONTROL, PIT and TAU provided to eligible Soldiers, pre and post data gathered until 1,600 participants enrolled**

PROGRESS: Early in this quarter Soldiers in the 3rd BCT continued to be the primary population enrolled into the study. We also, as has been the case previously, enrolled smaller numbers of Soldiers from other Brigades. **At the close of the quarter, a total of 1,533 consented Soldiers had been randomized to one of the four conditions (an increase of 91 since last quarter).** Regarding total enrollment, 385 participants were randomized to the TAU condition; 384 to the PIT condition; 381 to the CONTROL condition, and 383 to the RESET condition. Six group-based trainings were held during this quarter, and were delivered by one of two certified trainers (Dr. Joanne Fordiani or Nicole Delgado, M.A.). Baseline, pre-training, and post-training data were gathered from participants at these group sessions. At this time, we had a request pending to cap enrollment at 1,533 as we had exhausted enrollment from our primary Brigades prior to meeting the target of 1,600 enrolled participants (which was approved).

- **1 month follow-up data collection continues until complete**

PROGRESS: Follow up questionnaires were sent to participants with a valid mailing address who completed the in-person baseline visit and were enrolled through the month of May 2013 (1,533 participants). To date, a total of 692 completed follow-up questionnaires (a 46% return rate) had been received. As per study procedures, reminder phone calls were made by study staff to participants whose follow-up data were overdue for return.

- **Scanning of collected data continues until complete**
- **Final dataset received from Camber Corporation**

PROGRESS: We continued to be pleased with the work performed by Camber Corporation. Scanning had shifted to almost exclusively the second cohort (800 Soldiers from 3rd BCT). We continued to receive small numbers of completed follow up questionnaires from the original cohort of 800 Soldiers (mainly 10th CAB Soldiers), and those continued to be scanned in an ongoing fashion as they were received. To date, Camber Corporation had scanned and compiled baseline data for all 1,533 enrolled participants into an SPSS-compatible dataset. Once enrollment is officially closed, we planned to coordinate with Camber Corporation to determine a reasonable date to cease their processing of follow up questionnaires and deliver a final dataset. Any follow up questionnaires received after that date would be hand entered into the dataset by study staff. We anticipate this will be achieved in the next quarter.

- **Research technician compiles data codebook and transcribes intrusive thoughts**

PROGRESS: This milestone (which was carried over from previous quarters) had not been met. At this time, duties of the one full time Research Technician employed by this project did not allow time for these activities to be undertaken. We were optimistic that with the assistance of two Boston University volunteers, as well as supplemental funding to hire additional staff, we would be able to complete these objectives in the near future.

- **Statistician begins preparations for analyses**

PROGRESS: This milestone (which was carried over from previous quarters) had not been met. Study staff had conducted some very preliminary, non-complex analyses. We were in the process of preparing to present updated data at the MOMRP Resilience IPR to be held at Ft. Detrick August 27th and 28th, 2013. Plans to hire a dedicated statistician for this project as soon as the anticipated supplemental funding had been approved were in progress; to this end, we had met with an available biostatistician about this upcoming position and we were poised to begin the hiring process.

- **Additional activity during this quarter:**

- We had one personnel change during this quarter. Nicole Delgado, Research Technician, left study staff on May 29th 2013 after fulfillment of her one year contract. She was replaced by Nina Medoff, B.A.. Ms. Medoff's one year term of employment began on June 17th, 2013. She was initially hired at 30 hours per week as a short-term cost saving measure.
- An internal quality assurance audit of informed consent documentation for the 327 most recently consented participants was underway. This internal audit covered all consent forms (VHABHS Informed Consent Form, HIPAA Form, and Army Form DA-5303—

Volunteer Agreement Affidavit). We anticipated that this audit will be complete in early September 2013.

- We worked to resolve an issue with our participant remuneration (gift cards). We were optimistic that we would be able to issue replacement gift cards to all affected study participants in the coming quarter. These new cards would be provided by the vendor and there would be no cost to the study for remedying this error made by the issuing bank.
- We interviewed and selected two Boston University undergraduate students to serve as volunteers on this study (15 hours per week for a minimum of one semester). This would assist us with meeting pending milestones related to qualitative data. We anticipated that the local approval process for these student volunteers would be complete in early September, 2013.
- VHABHS activity during this quarter included one amendment to add/remove study staff. Specifically, Nina Medoff, B.A. (Research Technician) and Lisa Sochar (a new staff member at Camber Corporation, where data were scanned) were added, and Nicole Delgado, M.A. was removed. This amendment was reviewed and approved on July 8th, 2013.

Award Period 4, Months 4-6

- **1 month follow-up data collection continues until complete**

PROGRESS: All participants with a valid mailing address who completed the in-person baseline visit had been sent follow up questionnaires. **At this point, we had received a total of 708 completed follow-up questionnaires (a 47% return rate).**

- **Scanning of collected data continues until complete**
- **Final dataset received from Camber Corporation**

PROGRESS: During the month of October 2013, we coordinated with Camber Corporation to determine a reasonable date to cease their processing of follow up questionnaires and deliver a final dataset. They completed scanning of all returned follow up questionnaires effective October 16th, and compiled a final dataset (received by the study team October 24th). We continued to receive very small numbers of completed follow up questionnaires (<5 per month), and those were hand-entered into the dataset (and quality controlled) by study staff in an ongoing fashion.

- **Research technician compiles data codebook and transcribes intrusive thoughts**

PROGRESS: This milestone (which was carried over from previous quarters) had not been fully met although we were pleased to report that progress on this milestone was underway. We anticipated that the data codebook would be compiled in the upcoming quarter by the statistical staff (hiring process begun as discussed in previous quarter's summary above). Regarding the transcription of intrusive thoughts, this process began with the assistance our two Boston University volunteers; we anticipated the completion of this milestone in the coming quarter.

- **Statistician begins preparations for analyses**

PROGRESS: This milestone (which was carried over from previous quarters) had not been met. Study staff (Drs. Shipherd and Fordiani) did present preliminary findings at the MOMRP Resilience IPR held at Ft. Detrick August 27th and 28th, 2013 (see attached slides). Preparations for analyses would be underway following the hiring of statistical support staff in the coming months.

- **Additional activity during this quarter:**

- We had two personnel changes during this quarter. Following receipt of supplemental funding, we increased Research Technician Nina Medoff's effort on this study from 30 hours/week to 40 hours/week. This change was effective October 14th, 2014. Additionally we hired Alexis Matza, Ph.D. at 50% effort effective October 1st, 2013. Dr. Matza's area of expertise is qualitative data analysis, and she would be spearheading the effort to analyze the Phase 2 qualitative data (identified intrusive thoughts).
- An internal quality assurance audit of informed consent documentation for the 327 most recently consented participants was completed. Five inconsistencies discovered during the audit were reported to the VHABHS IRB, and these inconsistencies were noted by the IRB with no further action required. This internal audit was followed by a formal ICF audit by the local Research Compliance Officer; this formal audit was completed on October 24th. We are very pleased to report that there were **zero** inconsistencies found during this audit.
- We were pleased to report that our efforts to resolve an issue with our participant remuneration (gift cards) were successful. We would able to issue replacement gift cards to all affected study participants in the coming quarter; as we anticipated, these new cards were provided by the vendor and there was no cost to the study for remedying this error made by the issuing bank.
- Effective September 5th, 2013, two Boston University undergraduate students (Emily Singer and Chelsea Mencio) began work as volunteers on this study (15 hours per week, each). They would primarily assist with transcription and coding of qualitative data.
- We began the process of preparing documentation for our annual VHABHS Continuing Review. We anticipated that this documentation would be submitted in mid-November; following local approval and study renewal, we planned to submit this documentation for HRPO review.

- VHABHS activity during this period included two amendments. Specifically, 1) Emily Singer and Chelsea Mencio (volunteers) were added to the study protocol; this amendment was reviewed and approved on October 7th, 2013 and 2) a request to add procedures for the close of study enrollment (e.g. notifying Soldiers who were interested in the study but had not yet participated) was reviewed and approved on October 21st, 2013.

Award Period 4, Months 7-9

- **Statistical team compiles quantitative data codebook**
- **Statistical team begins preparations for analyses**

PROGRESS: These milestones (which were carried forward from previous quarters) were not been fully met although we were pleased to report that progress on both of those milestones was underway. The statistical team from Camber Corporation began work to compile the codebook, and were also preparing for data analyses (familiarizing themselves with background literature, beginning to write scoring syntax, etc.). We were optimistic that these two milestones would demonstrate significant progress during the coming quarter.

- **Data cleaning and checking**
- **Primary data analyses begin**

PROGRESS: The first of these two milestones was in progress but had not been fully met; as described, Camber Corporation employees had begun working with the dataset and had initiated the process of data cleaning/checking (i.e. examining variables for outliers, normal distributions, etc.). We anticipated that this milestone would be fully met during the coming quarter. Once the data cleaning and checking is complete, primary data analyses will begin.

- **Qualitative team transcribes intrusive thoughts**
- **Qualitative team develops coding scheme**

PROGRESS: Under the direction of Alexis Matza, Ph.D., qualitative team lead, this milestone was completed with the assistance our two Boston University volunteers. At this time, the development of a coding scheme was in progress and it was anticipated that progress would be made on this milestone during the coming quarter.

- **Additional activity during this quarter:**

- We had one personnel change during this quarter. In the previous quarter, we hired Alexis Matza, Ph.D. (at 50% effort effective October 1st, 2013) to spearhead the effort to analyze the Phase 2 qualitative data (identified intrusive thoughts). Effective January 1st, 2014, Dr. Matza's effort on this project was reduced to 25% as we have been able to supplement the qualitative analysis efforts with two no-cost Boston University volunteers

as described above. Emily Singer and Chelsea Mencio were both approved to begin work on the protocol as of October 7th, 2013.

- Documentation for our annual VHABHS Continuing Review was submitted to our local VHABHS IRB November 18th, 2013. We are pleased to report that we received approval of this documentation and a one year renewal on December 16th, 2013. Following this local approval and study renewal, we submitted this documentation for HRPO review on January 9th, 2014 and received acknowledgment from HRPO on January 21, 2014.
- An amendment adding Camber staff to the study was submitted to the local VHABHS IRB. The amendment added 7 staff members (Kellie-Ann French, Stephen Gutner, Sarah Morrisey, Klainie Nedoroscik, Miriam Plaza, Alexandra Steiner, and Noah Sulman). This amendment was approved January 6th, 2014. We anticipated that there would be at least two additional Camber staff added to the protocol in the coming quarter.
- The NIH Certificate of Confidentiality for this study was due to expire on December 31, 2013. On November 13th 2013, a request for an extension of this Certificate was initiated. The extension was granted by the NIH on December 27, 2013, with a new expiration date of December 31, 2015.

Award Period 4, Months 10-12

- **Statistical team compiles quantitative data codebook**
- **Statistical team begins preparations for analyses**

PROGRESS: The first of these milestones (which was carried forward from previous quarters) continued to be in progress, as the development of the quantitative codebook continued as Camber Corporation progressed through the phases of data analysis. The second of these milestones was been fully met; preparation for data analyses (including familiarizing themselves with background literature and writing of scoring syntax) is complete.

- **Data cleaning and checking**
- **Primary data analyses begin**

PROGRESS: The first of these two milestones was fully met; as described, Camber Corporation employees completed preparation of the data for analyses and also completed the process of data cleaning/checking (i.e. examining variables for outliers, normal distributions, etc.). Primary data analyses began, and we anticipated that these primary analyses would be completed during the upcoming quarter.

- **Qualitative team transcribes intrusive thoughts**
- **Qualitative team develops coding scheme**

PROGRESS: Under the direction of Alexis Matza, Ph.D., qualitative team lead, the first milestone above was completed with the assistance our two Boston University volunteers. We were also pleased to report that the development of a coding scheme was also completed during this quarter.

- **Additional activity during this quarter:**

- An amendment adding on additional Camber staff member (Burak Aydin) to the study was submitted to the local VHABHS IRB. This amendment was approved February 10th, 2014. We anticipated that there would be at least one additional Camber staff added to the protocol in the coming quarter.

Award Period 4, Months 13—15

- **Statistical team compiles quantitative data codebook**

PROGRESS: This milestone (which was carried forward from previous quarters) continued to be in progress, as the development of the quantitative codebook continues as Camber Corporation progresses through the phases of data analysis.

- **Primary data analyses continue**

PROGRESS: Primary data analyses were underway and we anticipated that these primary analyses would continue during the upcoming quarter.

- **Qualitative team codes data**

PROGRESS: We were pleased to report that under the direction of Alexis Matza, Ph.D., qualitative team lead, this milestone was met and all qualitative data had been coded. Dr. Matza was in the process of quality controlling this data in preparation for analyses and manuscript writing.

- **Manuscript preparation begins—Phase 1**

PROGRESS: Drs. Shipherd and Fordiani were in the process of preparing a manuscript highlighting Phase 1 findings.

- **Additional activity during this quarter:**

- We had one personnel change during this quarter. The last day of Nina Medoff, research technician, was June 7th, 2014.

Key Research Accomplishments

During this Award Period, data collection for 1,533 Phase 2 participants was completed and analysis begun. Dissemination began, and included:

- Drs. Shipherd and Fordiani presented updated data at the MOMRP Resilience IPR held at Ft. Detrick August 27th and 28th, 2013. The slides for this presentation are attached for your review.
- Drs. Shipherd, Fordiani, Matza, and Nina Medoff presented a poster using baseline data from the study at the second annual Joining Forces TBI/PTSD Conference held at Boston University on December 11th, 2014. This poster is included with this report for your review.
- Drs. Shipherd and Fordiani prepared and submitted a manuscript about mindfulness interventions to the journal Cognitive and Behavioral Practice which include a portion of Phase 1 (focus group) descriptive data from this study. An acceptance notification was received on June 9th, 2014. We are attaching the manuscript for you to review.
- Drs. Shipherd and Fordiani have begun working on a manuscript which will highlight additional findings from Phase 1 (focus group) analyses.

Conclusion

We are very pleased to report that this has been an extraordinarily productive year for the study. Data collection was completed, and with the supplemental funding that was awarded, we were able to hire statistical support as well as a research technician. We were able to continue our working relationship with Camber Corporation, and have been pleased with the ongoing work that they have been doing on our statistical efforts. Additionally, we have been able to make significant progress regarding the transcription and coding of our qualitative data (intrusive thoughts). This included the addition of a qualitative expert (Dr. Alexis Matza, Ph.D.) and two no-cost volunteers to the study. Analyses for the primary hypotheses are underway, however we have already begun to synthesize and disseminate preliminary findings via a presentation, a poster, and a completed manuscript. Another Phase 1 manuscript is in progress. Additionally, at the time of this report, a Phase 2 manuscript is in the planning stages and we anticipate that we will proceed quickly with additional dissemination. Finally, we are exceptionally pleased that we have been able to meet the milestones outlined in the SOW to this point and look forward to completing all milestones in the coming year, thanks in large part to the granting of additional funding as well as the ability to extend our period of performance for an additional no-cost year.

Publications, abstracts, and presentations: See Key Research Accomplishments

Inventions, patents and licenses: Nothing to report

Reportable outcomes: See Key Research Accomplishments

Other achievements: Nothing to report

References: None

Appendices

A. Statement of Work

B. Presentation slides from MOMRP Resilience IPR held at Ft. Detrick August 27th and 28th, 2013.

C. Poster presented at Joining Forces TBI/PTSD Conference held at Boston University on December 11th, 2013.

D. Cognitive and Behavioral Practice manuscript authored by Drs. Shipherd and Fordiani: Shipherd, J.C. & Fordiani, J. (in press). The Application of Mindfulness in Coping with Intrusive Thoughts Cognitive and Behavioral Practice. *Cognitive and Behavioral Practice*.

STATEMENT OF WORK

For ease of review, completed milestones are shaded in grey below:

Period 1 Milestones: Administrative committee reviews including the VA Boston Healthcare System's IRB and R&D committees with Human Research Protection Office (HRPO) will provide Second Level Oversight IRB approval. Similarly, a Federal Certificate of Confidentiality will be obtained within the initial startup period. Hiring of staff through the not-for-profit organization (BVARI) typically takes 4 months. Preparation of the content of RESET and CONTROL will be finalized in regular meetings with the investigation team, with particular input from Dr. Walser on how to train acceptance of thoughts. Military perspective will be provided by Drs. Benham and Barry who are familiar with the target audience. DoD perspective optimizing the training feasibility and adherence to the Comprehensive Soldier Fitness format will be provided by Drs. Adler and McGurk. Focus group feedback about RESET and CONTROL content will take place with 4 small group sessions of 12-15 Soldiers (total n = 20) reviewing the material to assure user acceptability. Hiring of Fort Drum Trainer will occur.

Period 2 Milestones: Training of trainers will continue at VA Boston. VABHS IRB and HRPO approvals will be obtained for final versions RESET and CONTROL trainings. Scannable versions of questionnaire packets will be finalized and printed. Data collection will be initiated for Phase 2. All data collection will take place via groups at the Ramada Inn, Watertown NY. All waves of data collection will take place over 7-10 day periods where project staff will be on site. Follow up data collection via mailed questionnaires will occur 1 month post completion of RESET, CONTROL, PIT or TAU. At least once per month, 7-10 day data collection trips will occur in Periods 2 and 3, with participants being randomized and completing the RESET, CONTROL, PIT or TAU.

Period 3 Milestones: Conservatively, data collection will be completed with at least 700 primarily 10th Combat Aviation Brigade participants who complete the initial training by Months 1-4 of period 3. It is likely that only partial data (no follow-up data) will be available for roughly another 100 of these participants due to scheduling constraints and general attrition. A recruitment trip coordinated with the timing of PDHRA briefings for the 3rd BCT will occur in Month 4 of Period 3. Utilizing additional funding, scannable versions of questionnaire packets will be printed to enroll a maximum of an additional 800 participants. Data collection with the 3rd BCT will begin in Month 4 of Period 3 with the goal of randomizing 3rd BCT participants to RESET, CONTROL, PIT, or TAU groups. Baseline, pre-training, post-training, and follow up data collection for these participants will continue through months 9-12 of this period.

Period 4 Milestones: Data collection (baseline and follow-up) and data scanning will continue through the award period until eligible and interested Soldiers in the targeted Brigades have been enrolled (1,533 Soldiers) and one-month follow-up data is complete. During Months 5-8, a final dataset will be received from Camber Corporation and hiring of the statistical team will begin. Once hired, statistical team will begin the compilation of the data codebook. The team will then begin preparation for analyses (writing of syntax, etc.) during this period. Also during this period, the qualitative team will transcribe the intrusive deployment thoughts. During months 9-12, data cleaning and checking by the statistical team will begin. Also during this time, primary quantitative data analyses will begin. The qualitative team will develop the coding scheme. During Months 13-16, primary qualitative data analyses will continue and manuscript preparation will begin. The qualitative team will code the intrusive thoughts. During months 17-20 and 21-24, data analyses and manuscript preparation continues and dissemination of findings to the scientific community begins. During months 25-28, the study team will also 1) report findings to Ft. Drum and debrief Ft. Drum leadership and 2) continue to disseminate findings to the scientific community.

PERIOD 1	Months 1-4	Months 5-8	Months 9-12
PHASE 1	<ul style="list-style-type: none"> • Hiring of staff, administrative work • Certificate of Confidentiality • VA IRB/R&D paperwork • Establish bi-weekly conference calls with all project personnel • Discuss content of trainings 	<ul style="list-style-type: none"> • Finalization of IRB approval • Meetings with Fort Drum Leadership for feedback • Ongoing bi-weekly conference calls with all project personnel • Continued refinement of RESET and CONTROL content 	<ul style="list-style-type: none"> • HRPO application • Finalization of RESET and CONTROL content for focus group • Hiring of the Fort Drum Trainer • Plan focus group recruitment • Training of trainers begins
	Months 13-16	Months 17-20	
PHASE 2	<ul style="list-style-type: none"> • Finalization of HRPO approval • Training of trainers continues • Recruitment of focus group participants via announcements and advertisements • Conduct 2 focus groups • Gather data from focus groups on content, utility and acceptability of RESET and CONTROL • 1 month follow-up data collection 	<ul style="list-style-type: none"> • Review qualitative and quantitative data gathered from first 2 focus groups • Conduct another 2 focus groups with feedback on RESET and CONTROL • Gather data from focus groups on content, utility and acceptability of RESET and CONTROL • 1 month follow-up data collection • Review qualitative and quantitative data gathered from second 2 focus groups 	
PERIOD 2	Months 1-4	Months 5-8	Months 9-12
PHASE 2	<ul style="list-style-type: none"> • Refine RESET and CONTROL content based on focus group feedback and data collection • Secure IRB/HRPO approval for final versions of RESET and CONTROL content • Randomize Companies to training condition: RESET, CONTROL, PIT, TAU • Recruitment efforts 	<ul style="list-style-type: none"> • RESET, CONTROL, PIT and TAU provided, pre and post data gathered • 1 month follow-up data collection • Recruitment efforts 	<ul style="list-style-type: none"> • RESET, CONTROL, PIT and TAU provided, pre and post data gathered • 1 month follow-up data collection • Continued recruitment efforts • 800 additional scannable questionnaire workbooks printed
PERIOD 3	Months 1-4	Months 5-8	Months 9-12
PHASE 3	<ul style="list-style-type: none"> • RESET, CONTROL, PIT and TAU provided to already recruited participants, pre and post data gathered • Recruitment of 3rd BCT begins • Delivery of RESET, CONTROL, PIT and TAU to 3rd BCT participants begins, pre and post data gathered • 1 month follow-up data collection continues for already recruited participants, begins for 3rd BCT • Scanning of collected data continues for already recruited participants, begins for 3rd BCT • Continued recruitment efforts 	<ul style="list-style-type: none"> • RESET, CONTROL, PIT and TAU provided to 3rd BCT participants, pre and post data gathered • 1 month follow-up data collection continues • Continued recruitment efforts • Scanning of collected data continues 	<ul style="list-style-type: none"> • RESET, CONTROL, PIT and TAU provided to 3rd BCT participants, pre and post data gathered • 1 month follow-up data collection continues • Scanning of collected data continues
PERIOD 4	Months 1-4	Months 5-8	Months 9-12
PHASE 3	<ul style="list-style-type: none"> • RESET, CONTROL, PIT and TAU provided to eligible Soldiers, pre and post data gathered until 1,533 participants enrolled • 1 month follow-up data collection continues until complete • Scanning of collected data continues until complete 	<ul style="list-style-type: none"> • Hiring of Statistician and Research Technician • Final dataset received from Camber Corporation • Statistical team compiles quantitative data codebook • Statistical team begins preparations for 	<ul style="list-style-type: none"> • Data cleaning and checking • Primary data analyses begin • Qualitative team develops coding scheme
			Months 13-16

		analyses • Qualitative team transcribes intrusive	• Primary data analyses continue
PERIOD 4	Months 17-20	Months 21-24	Months 25-28
PHASE 3	<ul style="list-style-type: none"> Primary data analyses continue Secondary/exploratory data analyses begin Manuscript preparation continues- Phase II Qualitative manuscript preparation begins Dissemination of findings to scientific community begins 	<ul style="list-style-type: none"> Secondary/exploratory data analyses continue Manuscript preparation continues- Phase II Dissemination of findings to scientific community continues 	<ul style="list-style-type: none"> Manuscript preparation continues- Phase II Dissemination of findings to scientific community continues Report to Fort Drum with findings Debriefing with Fort Drum leadership

Enhancing Post-deployment Training: Preventing PTSD by Coping with Intrusive Thoughts

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&

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National Center for PTSD
Women's Health Sciences Division
Boston University School of Medicine**

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Disclaimer: Preliminary data and doesn't represent
views of DoD, VA, WRAIR, NCPTSD, etc

Study Development & Rationale

- Study Development
 - Development of PTSD in returning Soldiers is a salient challenge for the Army
 - Secondary prevention would be ideal (versus treatment)
- Rationale
 - Following trauma, intrusive thoughts (IT) are expected
 - Coping with IT can influence their trajectory
 - 75% of a pilot sample of returning forces report intrusive thoughts about Iraq
 - CBT and Acceptance and Commitment Tx for PTSD may be able to be translated into skills

Study Development & Rationale

- ❑ This project is a secondary prevention program that teaches how to manage IT
- ❑ How to best manage IT raised several experimental questions...
 - Is psychoeducation enough?
 - Do Soldiers need skills to manage IT?
 - If skills are needed, what kinds of skills? (CBT, ACT)
- ❑ Why this study is unique
 - Capitalizes on pre-existing training infrastructure
 - Targets all Soldiers irrespective of symptoms: decreased stigma
 - Skills can be applied to other areas of life, increasing relevance

Aims/Hypotheses

Demonstrate:

- The viability of brief, easily implemented trainings to improve Soldiers' ability to cope with intrusive thoughts
- Possible to provide psychoeducation (PIT)
- Skills (CONTROL or RESET) are superior to Training As Usual or psychoeducation
- RESET skills are more effective long term

- TAU < PIT < CONTROL < RESET

Phase I: Development of trainings

- Focus Groups
- Piloted trainings Fall, 2010 – Spring, 2011
 - 20 Soldier participants
 - Provided Psychoeducation, RESET, and CONTROL
 - Main goals were increasing palatability and achieving maximum buy-in
- Findings
 - Encouraged small groups
 - Both groups practiced skills
 - Liked having CD's to practice with
 - Asked for information to give to buddies
- Led to revision of training material (language, deliverables, etc.)

Definition of intrusive thoughts

“Thoughts, memories, or images about any stressful experience, including deployment, that can pop into your mind repeatedly. Often these thoughts are annoying, and they might make it harder for you to concentrate or hard for you to get things done.”

Overview of TAU and PIT

- Training As Usual (TAU)
 - Comprehensive Soldier Fitness
 - Occurs within units, is provided by MRT
 - We ask about when TAU was given at baseline and 1-month follow-up
 - Provides referral information
- Psychoeducation (PIT)
 - **15-20 minute** training by study staff
 - Educates Soldiers about what intrusive thoughts are and normalizes these thoughts
 - Identifies when they are a problem
 - Provides referral information

Overview of CONTROL skills

Common intrusive or unwanted thoughts affect almost everyone

Only you can learn to control them

New skills can help you

Thoughts can be stopped

Remove your thoughts with more pleasant ones

Other activities will help distract you

Learning comes with practice: Train your skills!

Overview of RESET skills

Remember it is normal to have intrusive or unwanted thoughts.

Ease up on control, it doesn't always work well with thoughts.

See & accept your thoughts: You are more than just your thoughts.

Experience thoughts as they happen: Don't judge them.

Train your skills: Practice is important!

Exercise

**BEING LARGER THAN YOUR
THOUGHTS:
THE MOUNTAIN EXERCISE**



Phase II (RCT): Currently Underway Design and Methodology

- 1,533 Fort Drum Soldiers randomized to one of four conditions (TAU, PIT, CONTROL, RESET)
 - 10th Combat Aviation Brigade (? lower combat exposure)
 - 3rd Brigade Combat Team (? higher combat exposure)
 - Other Brigades (variable levels of combat exposure)
- 3-12 months deployment (PDHRA recruitment)
- One in-person baseline visit (off post) with multiple pre-post training assessments
- Mailed one month follow-up questionnaires, response rate with valid mailing address (1,509) = 47%

Sample intrusive thoughts

- Combat experiences—self or others
 - *The whistling of a mortar as well as the hum of a rocket flying over my head*
 - *Getting blown up by an IED*
 - *...images of my dead friends being wheeled to the Blackhawk that was taking their remains off the battlefield*
 - *Watching the death of 5 fellow Soldiers from my platoon*
- Concerns about family stateside
 - *That I would lose my son and/or my connection to him*
 - *Thoughts of my husband driving drunk with my daughter in the vehicle while I'm deployed*
- Leadership concerns/concerns about job performance
 - *The careless attitude of my commander and first sergeant..."*
 - *The thought of not being valuable to my unit*

Participant Flow

Cleaned dataset

N = 1,524

Randomization

TAU
385

PIT
384

RESET
377

CONTROL
378

Follow up data
received

170

155

166

152

Measures

- Demographics and combat exposure (WRAIR scale)
- Participant Satisfaction with training
- Frequency and distress associated with IT
- Posttraumatic Checklist (PCL)
- Depression Anxiety Stress Scale (DASS)
- Insomnia Severity Index (ISI)

- Several other measures were gathered but not presented here due to time constraints

Preliminary Findings

Demographic Characteristics	N=1,524	
Sex		
Male	90.6%	
Female	9.4%	
Age, years	28.5 mean (SD = 6.7; min/max = 19/56; mode = 26)	
Rank		
Private (PV1, PV2, PFC), Corporal, Specialist	56.2%	
Sergeant/Staff Sergeant	28.3%	
Sergeant (1 st Class/Master/Major)	6.1%	
Officer (1LT, 2LT, CPT, MAJ)	6.5%	
Warrant Officer (W1—W5)	3.2%	
Race		
Black/AA	14.0%	
White/Caucasian	61.8%	
Hispanic	15.6%	
Other	8.6%	
Total number of deployments	Mean=1.95 (min/max = 1/14)	

Preliminary Findings

- Combat Exposure (WRAIR Combat Scale, range = 0-29)



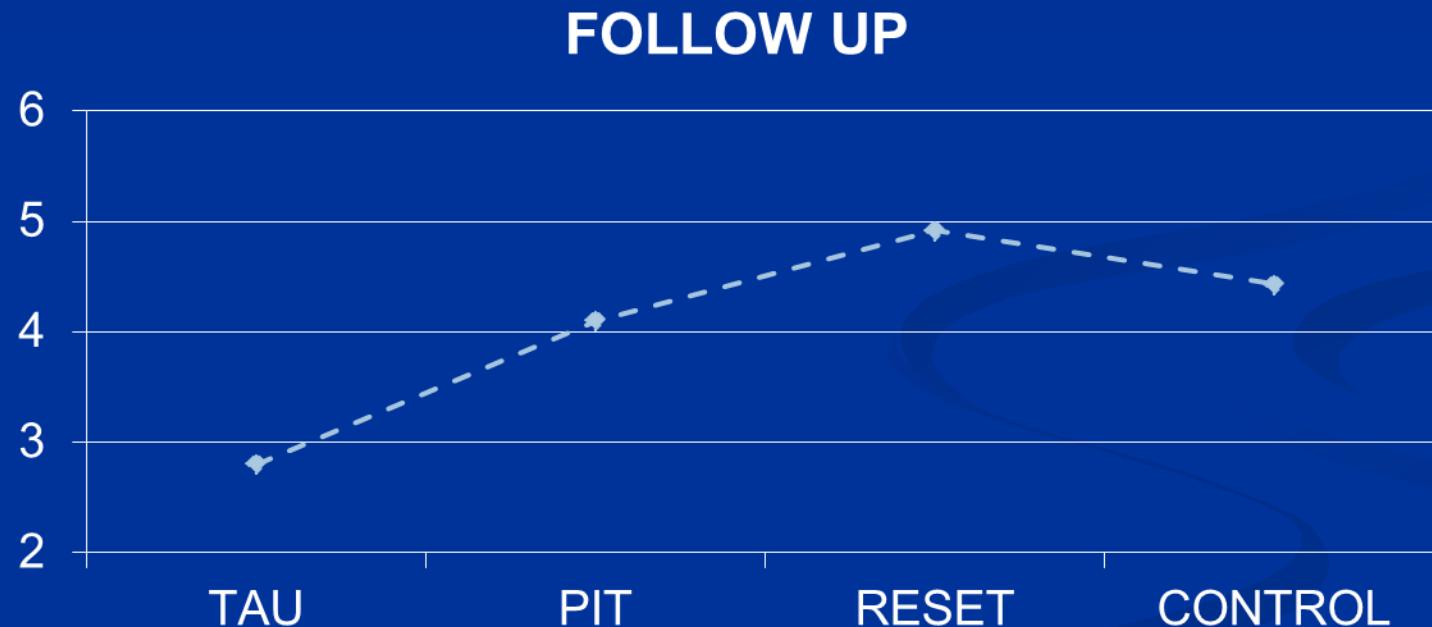
$$t(1,037) = -18.37, p < .001$$

- Multiple Regression analyses to test combat exposure effect of training type on outcomes revealed few effects**.

Satisfaction with Trainings

Expectancy of Treatment Outcome

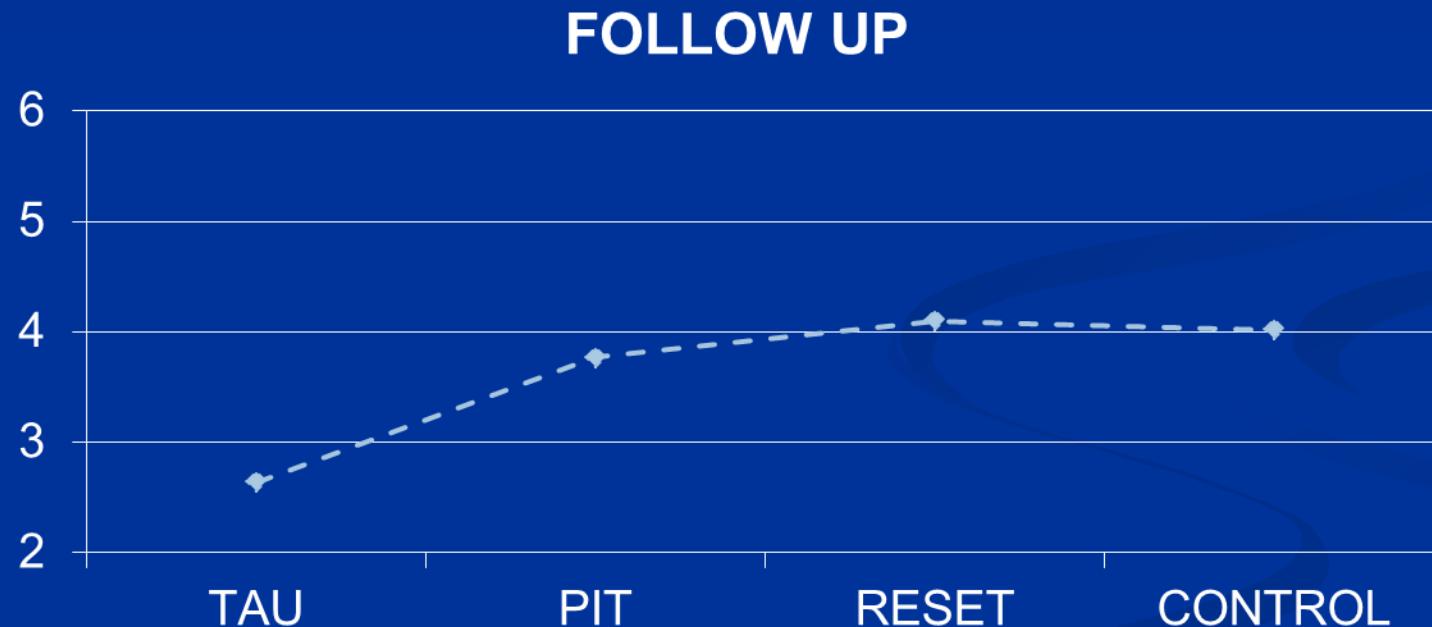
“Overall, how satisfied are you with this training?” (range = 0-8)



Satisfaction with Trainings

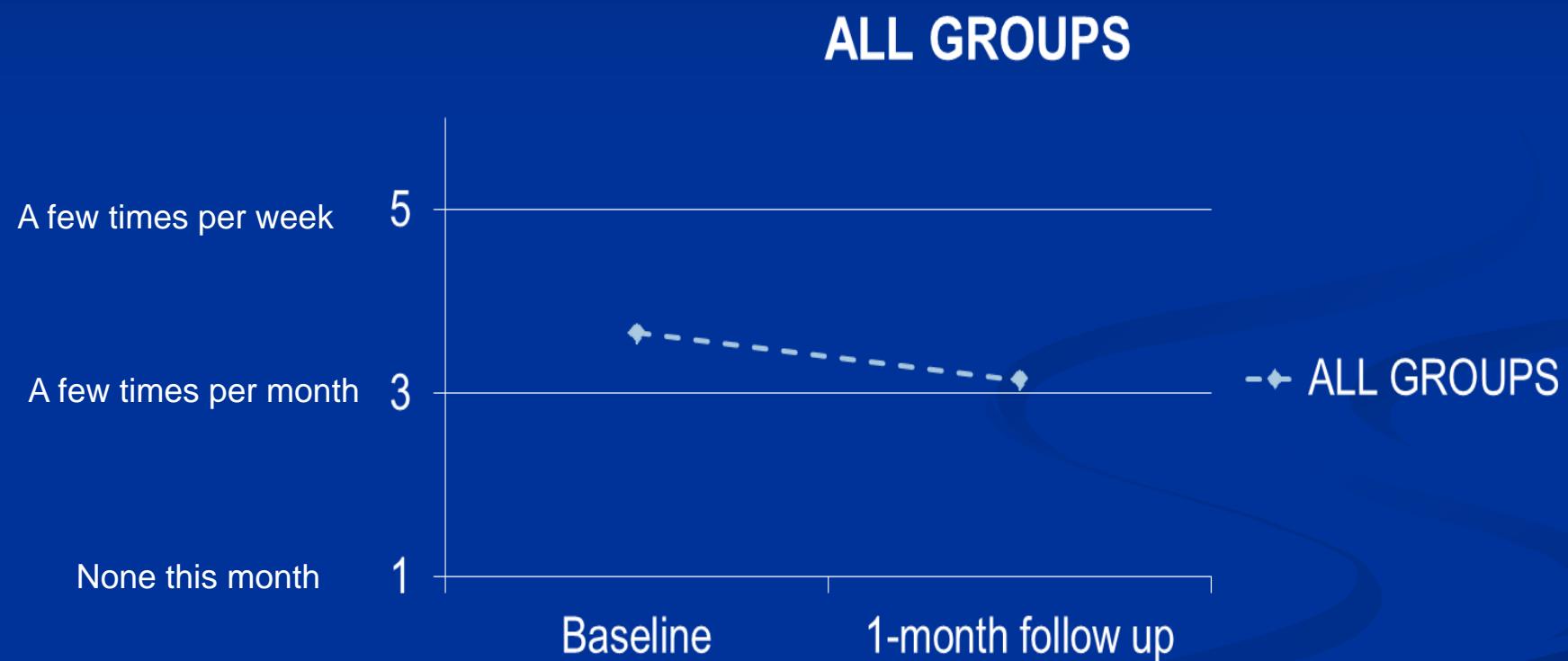
Expectancy of Treatment Outcome

“How useful has this training been to you?” (range = 0-8)



Preliminary Findings

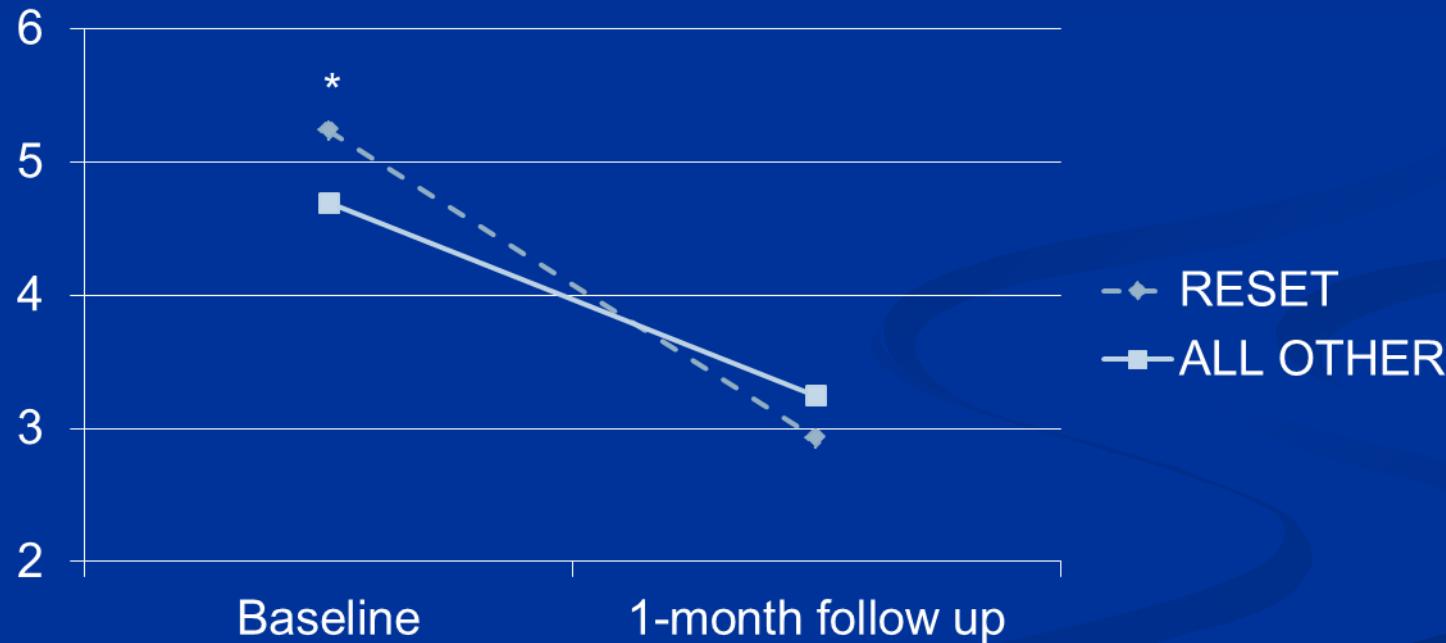
Frequency of intrusive thought past month



Preliminary Findings

Distress about intrusive thought past month

- 0-10 scale, higher is more distress

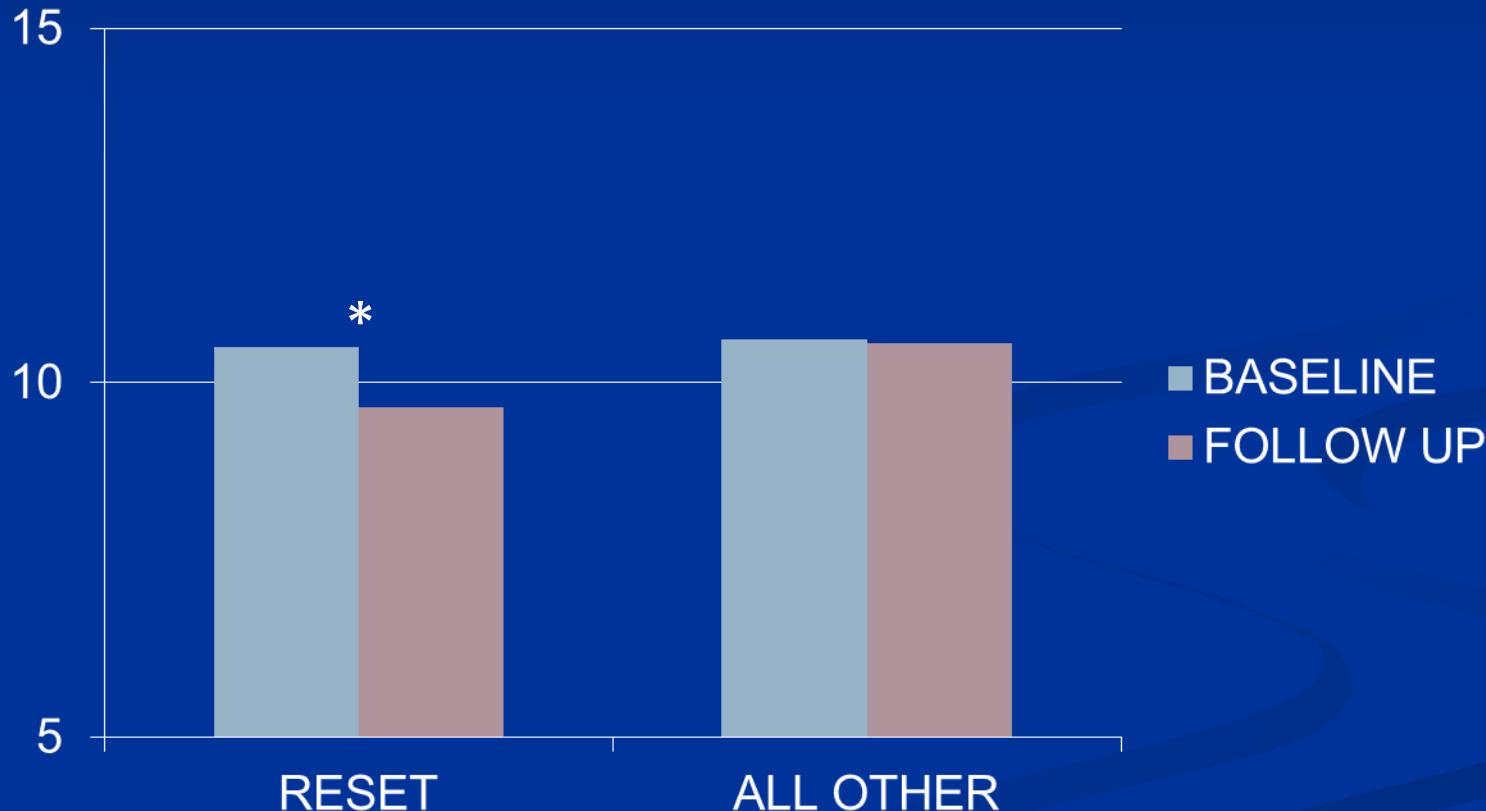


Group \times Time interaction $F(1,638) = 12.352$ $p = .000$, $\eta^2 = .019$

Preliminary Findings

PCL Arousal Subscale*

possible range = 5 to 25

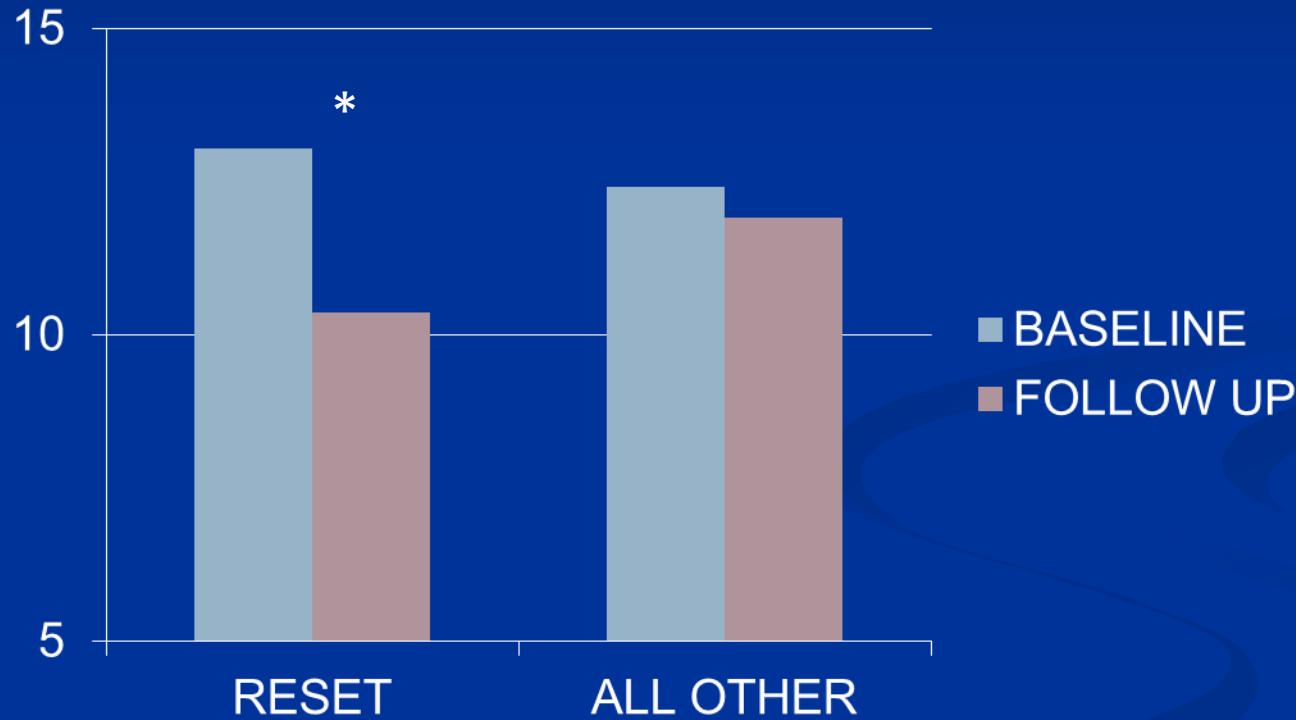


Group \times Time interaction $F(1,641) = 5.099$ $p = .024$, $\eta^2 = .008$

Preliminary Findings

DASS-Stress Subscale

possible range = 0 to 21

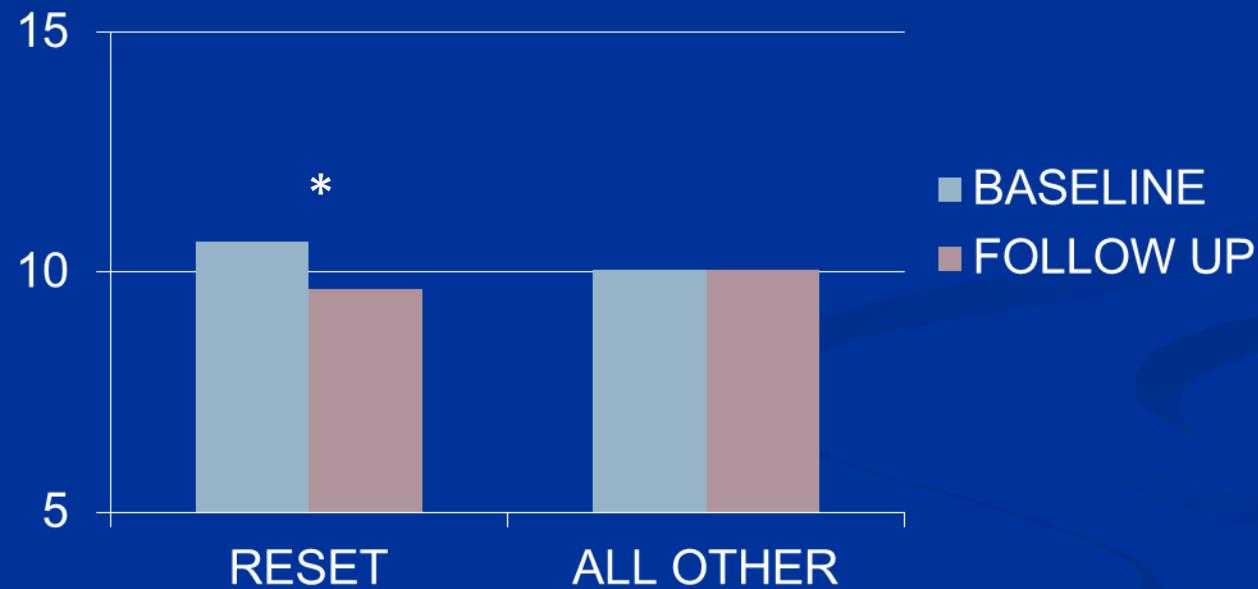


Group \times Time interaction $F(1,635) = 9.038$ $p = .003$, $\eta^2 = .014$

Preliminary Findings

Insomnia Severity Index

possible range = 0 to 20



Group \times Time interaction $F(1,631) = 4.739$ $p = .030$, $\eta^2 = .007$

Practice Effects

- There were no differences in the frequency of skill practice reported at follow up when comparing RESET and CONTROL skills groups
- On average, skills groups reported practicing about once per week.

Successes

- One hour of training is beneficial across various domains
- Three PowerPoint training modules finalized for delivery, including training manuals
- Well-received by Soldiers
- 1,533 of 1,600 participants enrolled
- Preliminary analyses show effects in hypothesized directions, with RESET showing greatest effectiveness in several domains

Current and Anticipated Challenges

- Significant implementation challenges early in Phase II
 - Eight month delay
 - Resolved in January, 2012 with redesign of study
- Recent/ongoing challenges regarding staffing
 - Statistical expertise needed for qualitative and quantitative analyses
 - Additional technician needed for administrative and organizational duties
 - Resolution via supplemental funding in process
- Recruitment of final 67 participants?
 - All interested/eligible participants from primary target Brigades have been recruited
 - Request to cap enrollment at 1,533 pending

Next Steps

- Qualitative analyses of Soldiers' identified intrusive thoughts
- Hiring of full time statistician to support more complex and nuanced quantitative analyses, including exploration of additional variables of interest:
 - Gender
 - Rank
 - Level of combat exposure
 - Type of intrusive thought
 - Soldiers with PTSD symptoms/diagnosis at time of enrollment

Dissemination

□ Dissemination to date:

- Presentation to the Women's Health Sciences Division of the National Center for PTSD
- Shipherd, J.C. & Fordiani, J. (2013, April). *RESET: Mindfulness Training for Soldiers*. Presented at the 11th Annual International Scientific Conference of the Center for Mindfulness in Medicine, Health Care, and Society, Norwood, MA.
- Fordiani, J. & Shipherd, J.C. (2012, March). *Enhancing Soldier Mindfulness: Preliminary findings from the RESET Study*. Poster presented at the 10th Annual International Scientific Conference of the Center for Mindfulness in Medicine, Health Care, and Society, Norwood, MA.

- Provision to the Army of final training modules, manuals, and other materials (CD's, wallet cards): dissemination ready
- Manuscripts and presentations in development
- Wrap-up with Fort Drum community

Gender Comparisons of Physical and Psychological Health in Active Duty Army Soldiers

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BACKGROUND

While gender differences on both physical and psychological health variables have been explored in civilian and Veteran populations, there is less investigation into gender differences on these variables within active duty Soldiers. Also, while women have been a part of the U.S. Military since its inception, most research on active duty (AD) soldiers and Veterans has focused on men. Despite a paucity of literature in AD populations, it has been found that women report greater exposure to MST, and men report greater exposure to combat experiences than women (Maguen et al., 2012). It has also been found that men report higher rates of probable deployment-related TBI (Iverson et al., 2013). Findings on physical and mental health gender differences in an AD sample have been inconsistent (Murphy et al., 1997; Smith et al., 2007), as have findings in research on PTSD rates and gender in this population. Some research has found no differences in reported PTSD symptoms (Maguen et al., 2012; Street et al., 2013), and some findings indicate that women are more likely than men to meet criteria for PTSD (Tolin & Foa, 2006). Regarding therapy utilization, while AD rates of mental health services usage are similar to usage rates in the general population, female AD Soldiers were found to be more likely than men to use mental health services (McKibben et al., 2013). This study sought to describe similarities and differences in a subset of physical health and psychological health variables across gender in an active duty Army population.

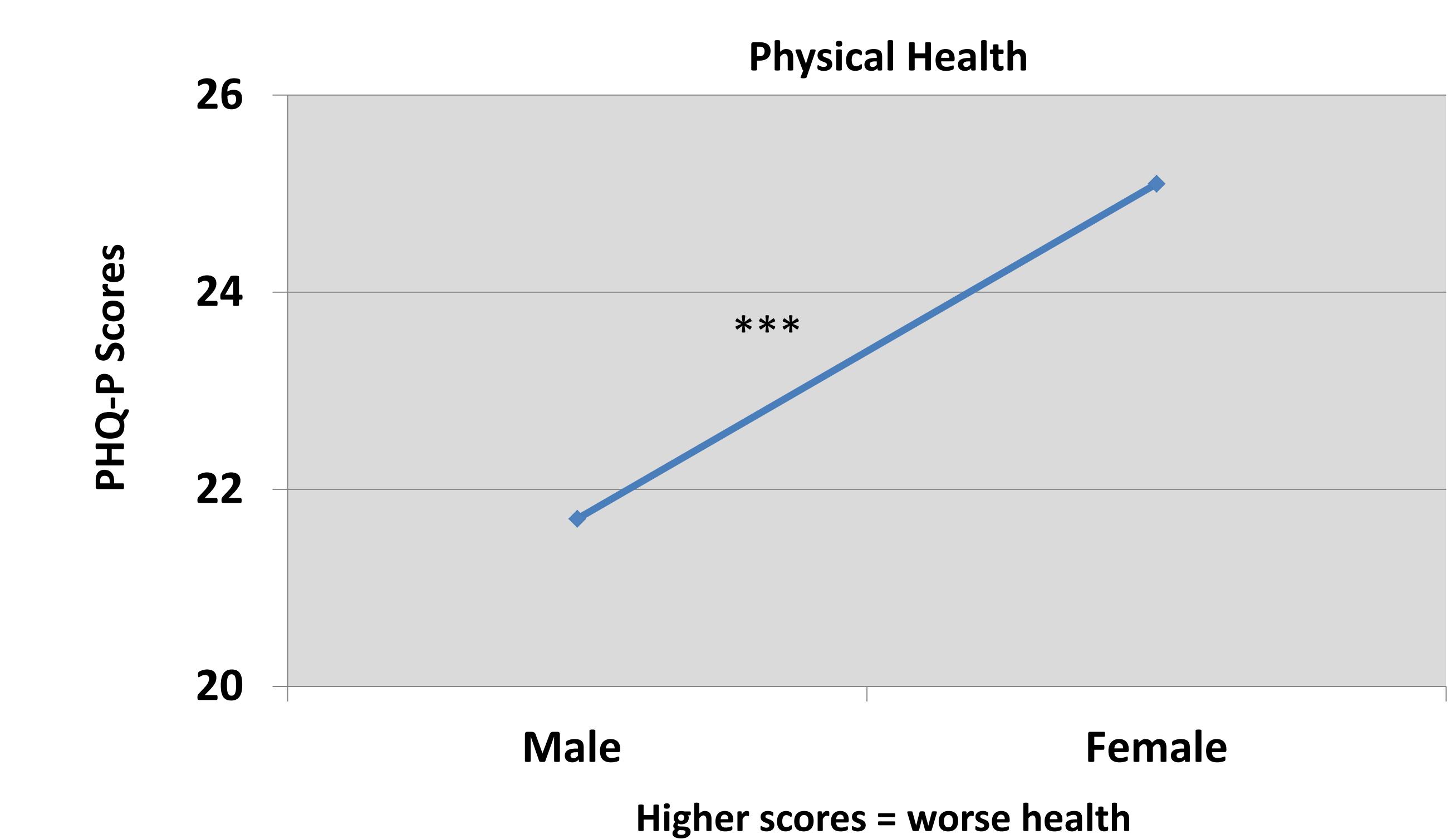
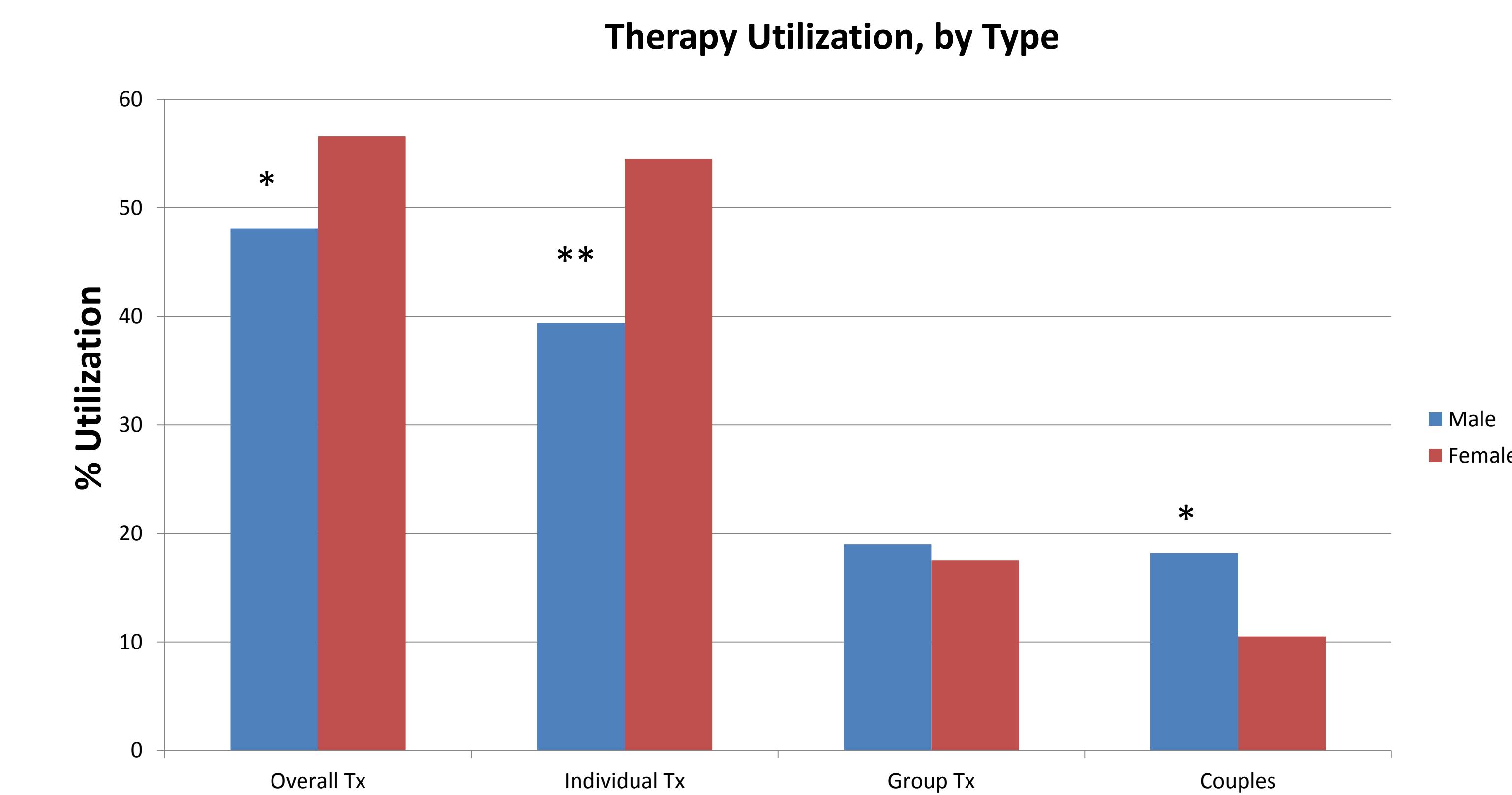
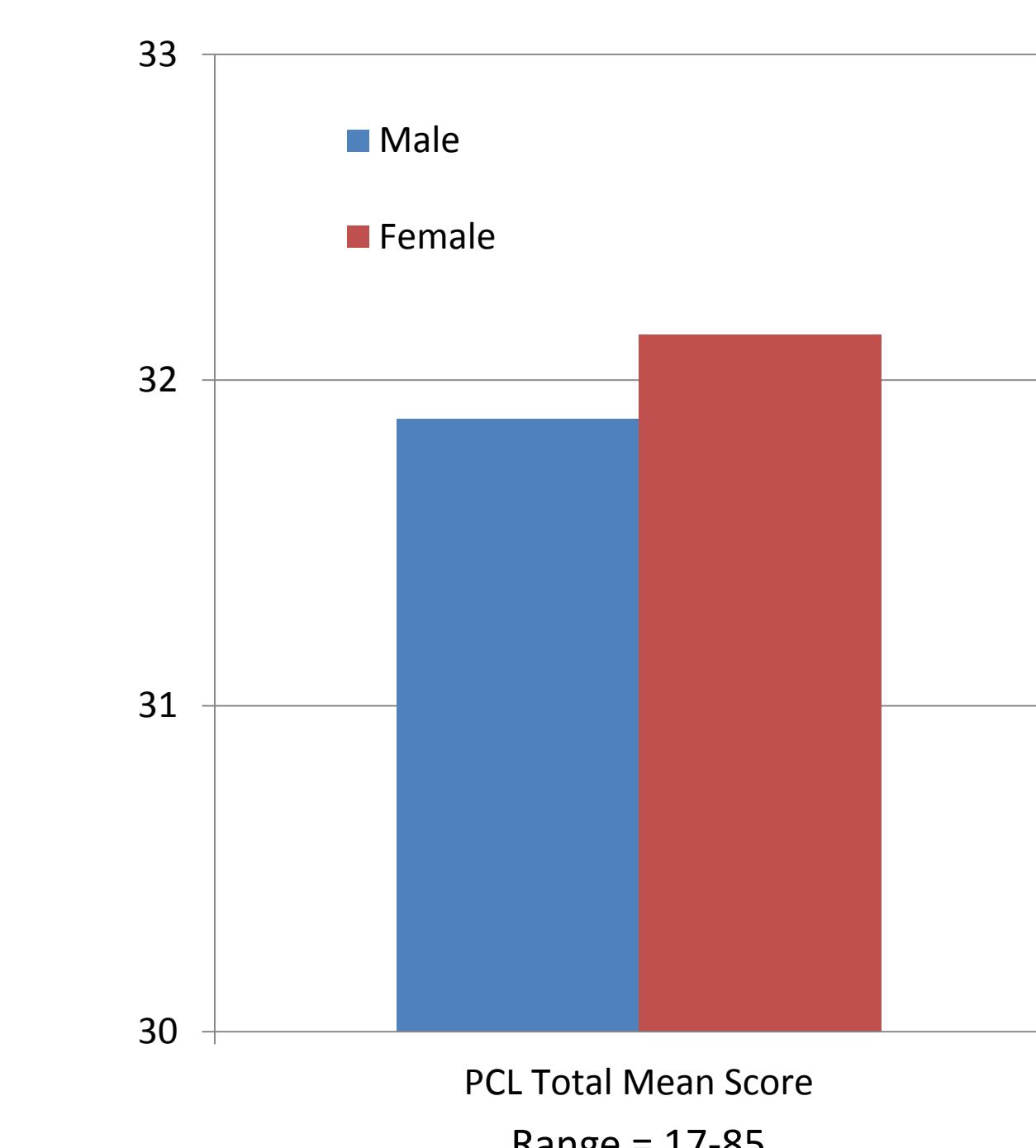
METHOD

1. Active duty Soldiers who returned from deployment within the past 12 months ($n=1,515$) were recruited from the Fort Drum, NY area.
2. At an in-person visit, Soldiers were asked to complete pencil-and-paper baseline questionnaires which included the WRAIR Combat Experiences Scale, 29-item version (CES; Wilk et al., 2010), Posttraumatic Checklist (PCL; Weathers et al., 1993), Physical Health Questionnaire (PHQ-P; Spitzer et al. 1999), MST items from the Deployment Risk and Resilience Inventory subscale G (DRRI; King et al., 2006), frequency of TBI-related events during all deployments, and psychotherapy utilization.



PCL Findings

- No differences in PTSD symptoms as measured by the PCL ($p > .05$)
- No significant differences on any of the PCL subscales (Reexperiencing, Avoidance, Arousal: $p > .05$)



CONCLUSIONS

- Consistent with previous research, men reported more combat exposure and TBI events, while women were more likely to report MST.
- No gender related differences were found in self-reported PTSD symptoms.
- Women tended to utilize mental health services at a higher rate, especially individual therapy; whereas men participated more in couples' therapy.
- Women self-reported poorer physical health.
- Further exploring these physical and psychological health gender similarities and differences would benefit providers in the treatment and care of Soldiers who have just returned from deployment.

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Abstract

Across a variety of disorders, clients present with clinically-significant intrusive thoughts. These thoughts can be problematic in their own right, with many clients reporting difficulty focusing on other therapeutic interventions due to problems with attention and increased distress that often accompany the experience of intrusive thoughts. Thus, cognitive-behavioral therapists can find value in learning thought management strategies that can be used with a variety of clients.

Despite the increase in attention within the scientific literature and popular media on mindfulness-based interventions, many clinicians are unaware that it is possible to bring these skills into therapy as an adjunct to ongoing CBT. Thus, we provide an overview of how to teach brief mindfulness skills (5-10 minute trainings). Video segments will highlight three skills in particular that have been found to be useful for coping with intrusive thoughts including 1) Observation of thoughts 2) Non-judgment of thoughts, and 3) Being larger than your thoughts. Data on the use of these skills with active duty Soldiers who experience intrusive thoughts from their most recent deployment are presented as an example.

Keywords: Mindfulness; training; intrusive thoughts; Acceptance and Commitment Therapy; meditation; skill building

Coping with Intrusive Thoughts: Skills Everyone Can Use

Submitted 1/31/14

Intrusive thoughts, which are common across a variety of disorders, can be defined as “*...any distinct, identifiable cognitive event that is unwanted, unintended, and recurrent. It interrupts the flow of thought, interferes in task performance, is associated with negative affect, and is difficult to control*

(Clark, 2005).” Specifically, these thoughts are typically short sensory flashes (most commonly visual), and are experienced with a sense of “now-ness” or happening in the present (although the individual usually does not lose awareness of other aspects of the present, as in a flashback; Hackman, Ehlers, Speckens, & Clark, 2004). These distressing cognitive events are a normative response to stressors, and are common in both nonclinical (Brewin, Dalgleish, & Joseph, 1996; Purdon and Clark, 1993) and clinical samples. Indeed, intrusive thoughts have been observed and studied in depression (Hall et al., 1997; Wenzlaff, 2002; Wenzlaff, Wegner, & Roper, 1988), anxiety disorders (Gross & Eifert, 1990; Ladouceur et al., 2000; Wells & Carter, 2001) insomnia (Harvey & Payne, 2002; Wicklow & Espie, 2000), and general medical conditions such as breast cancer and cardiac populations (Bennett & Brooke, 1999; Johnson Vickburg, Bovbjerg, DuHamel, Currie, & Redd, 2010; Ladwig et al., 1999; Lewis et al., 2001). While most cognitive-behavioral treatment programs are diagnosis-specific and teach clients skills to manage symptoms, it is possible that trans-diagnostic skills that can also provide benefit across a wide range of presenting complaints (Ellard, Fairholme, Boisseau, Farchione, & Barlow, 2010; Farchione et al., 2012). Learning effective strategies for coping with intrusive thoughts is one such skill.

Although intrusive thoughts are both expected and normative across varied populations, those experiencing intrusive thoughts often report that the thoughts are disturbing, and they fear

“going crazy” (Shipherd, Beck, Hamblen, & Freeman, 2000). When an intrusive thought occurs it can create emotional distress, physiological arousal, and interference with concentration or task completion lasting anywhere from minutes to hours. There are a multitude of strategies to assist in coping with intrusive thoughts, some that are designed to work in the short-term and some that are more effective in the long run. Avoidance-based strategies such as distraction, denial, suppressing overt emotion (e.g. trying not to cry), and suppressing the unwanted intrusive thoughts themselves (Lapp et al., 2010; Wheeler & Torres Stone, 2010) are quite common and can be effective for brief periods. However, suppression as a long term coping strategy can be problematic (e.g., Purdon, 1999; Purdon & Clark, 2000; Shipherd & Beck, 1999; Shipherd & Beck, 2005). Conversely, approach-based coping is more helpful to long term functioning (Shipherd & Salters-Pedneault, 2008) and is an important aspect of many empirically supported treatments.

Fortunately intrusive thoughts themselves, and the coping mechanisms that are commonly used to deal with them, can be targeted by clinicians during the course of treatment with resilient coping for intrusive thoughts being taught (Marcks & Woods, 2005). One potential approach-based strategy to target intrusive thoughts and their resultant symptoms is the use of mindfulness training, which has been shown to be effective at mitigating a variety of symptoms and has a rich foundation in the stress-management literature (e.g., Kabat-Zinn, 2005). Mindfulness-based stress reduction (MBSR; Kabat-Zinn, 2005) has been utilized across a wide variety of populations, both clinical and non-clinical, with positive results in a host of domains including depression, anxiety, chronic pain, alcohol misuse, and physical complaints (Hofmann, Sawyer, Witt, & Oh, 2010; Morone, Greco, & Weiner, 2008; Rosenzweig et al., 2010; Smith et al., 2011). MBSR is also used as a general stress reduction technique in non-clinical samples

(Shapiro, Brown, & Biegel, 2007; Shapiro, Schwartz, & Bonner, 1998). While traditional MBSR requires in-depth practitioner training and is typically delivered over the course of 12 weeks, it has been shown that mindfulness skills can be taught via brief 2-20 minute trainings. In these studies, brief education and metaphors delivered by novices result in decreased avoidance and struggles with intrusive thoughts or increased acceptance (Eifert & Heffner, 2003; Gutierrez, Luciano, Rodriguez, & Fink, 2004; Hayes et al., 1999; Keogh, Bond, Hanmer, & Tilston, 2005; Levitt, Brown, Orsillo, & Barlow, 2004; Masedo & Rosa Esteve, 2007). Thus, it is clear that brief training in acceptance and mindfulness-based skills can drastically alter clients' interpretations of thoughts and emotions and can reduce symptoms.

Metaphors and guided experiential exercises allow the individual to observe their thoughts from a more detached perspective rather than being fused with the thoughts and accompanying distress (Hayes, Masuda, Bissett, Luoma, & Guerrero, 2004), and are at the foundation of Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 1999). However, we argue that the exercises and metaphors can be a useful adjunct to other treatments, as they help the client see the thoughts as they are – just thoughts. Additionally, an ongoing sense of self (self-perspective) is established so that the individual can view him/herself as a “thinker” of thoughts. From this perspective, a context can be built wherein thoughts can be experienced without any need to suppress or avoid, but rather it becomes possible to observe the thoughts as they come and go. This process encourages meta-cognition rather than over-involvement with the maladaptive intrusive thoughts and their painful sequelae. Clearly this approach, which emphasizes increasing adaptive behaviors rather than focusing on problems, can be valuable across treatment of a wide variety of clinical presentations.

Within this framework, we developed and tested ACT-based mindfulness skills in an active duty Army population. These skills were packaged into a 50 minute, trainer-led PowerPoint-based presentation (the RESET training) which was designed to be consistent with the format and duration of mandated Army-wide training modules. Specifically, the RESET training focused on psychoeducation about intrusive thoughts and skills to cope with them, presented in an easy to remember acronym:

Remember it is normal to have intrusive thoughts.
Ease up on efforts to control, it doesn't always work well with thoughts.
See & accept your thoughts: You are more than just your thoughts.
Experience thoughts as they happen: Don't judge them.
Train your skills: Practice is important!

Embedded within the PowerPoint training were several short (5 minute) guided experiential exercises, participants were taught three strategies for accepting unwanted thoughts. Specifically, the three strategies were as follows:

1) Observing thoughts

((INSERT VIDEO CLIP))

2) Non-judgment of thoughts

((INSERT VIDEO CLIP))

3) Being larger than your thoughts

((INSERT VIDEO CLIP))

Soldiers and training for post-deployment intrusive thoughts

In a sample of 20 active duty Soldiers who were stationed at Fort Drum, NY the RESET skills were found to be effective when tested one month after the 50-minute training. Compared with Soldiers who received control-based skills, Soldiers learning mindfulness skills increased in both

acceptance ($F(2,26) = 3.78, p = .036$) and non-judgment of thoughts ($F(1,14) = 5.63, p = .033$).

These changes were noted across Soldiers with a variety of different intrusive thoughts including those specifically about combat experiences, worries about family, and concerns about finances. Improvement was also found on two of the three subscales of the Posttraumatic Maladaptive Beliefs Scale (PMBS; Vogt, Shipherd, & Resick, 2012), Self-worth ($F(1,14) = 13.72, p = .002$) and Reliability ($F(1,14) = 19.39, p = .001$), suggestive of increases in healthy meta-cognition. Looking qualitatively at participant data, participants reported engagement with the trainings (“*I've never done anything like it, never seen anything like it...it's definitely new and different*”, “*I was actually having fun!*”) as well as self-reported willingness to recommend the skills to other Soldiers (“*...should be offered to all Soldiers.*”) Additionally, Soldiers in leadership positions endorsed the utility of this training for troops they supervise (“*(RESET) will improve the lives of my Soldiers*”). Perhaps most relevant to CBT therapists is that Soldiers willingly practiced the mindfulness skills in the month post-training with only audio tracks to encourage the practice.

Discussion

It will come as no surprise to cognitive-behavioral therapists that people can change the way they interact with intrusive thoughts. What we suggest is that these changes can occur with extremely brief training that can be an important supplement to many clinical interactions. In fact, these concepts and the associated skills can be taught in the time equivalent to one clinical session, which makes their use particularly attractive for clinicians in busy, time-limited environments. It is important to note that while the Soldiers in the example provided were not recruited based on any particular clinical syndrome; all the Soldiers were able to identify troubling thoughts that continued to be bothersome in their daily lives up to one year post-deployment. As the Army can

be regarded as both a structured and a control-oriented environment, it is also noteworthy that even in this population, Soldiers who learned the mindfulness skills found them useful, liked and practiced them, and were even willing to endorse their use to other Soldiers. On several measures of acceptance, mindfulness, and cognition the Soldiers found benefit from the skills. Thus, it is reasonable to infer that these skills could be taught in as an adjunct to other treatments for a variety of clinical presentations.

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